

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

## (PCT Article 36 and Rule 70)

Applicant's or agent's file reference AP102061	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/FI2004/000688	International filing date (day/month/year) 17.11.2004	Priority date (day/month/year) 19.11.2003	
International Patent Classification (IPC) or national classification and IPC A61F6/18			
Applicant SCHERING OY et al.			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> <i>(sent to the applicant and to the International Bureau)</i> a total of 2 sheets, as follows:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</li> <li><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</li> </ul> <p>b. <input type="checkbox"/> <i>(sent to the International Bureau only)</i> a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Box No. I Basis of the opinion</li> <li><input type="checkbox"/> Box No. II Priority</li> <li><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li><input type="checkbox"/> Box No. IV Lack of unity of invention</li> <li><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li><input type="checkbox"/> Box No. VI Certain documents cited</li> <li><input type="checkbox"/> Box No. VII Certain defects in the international application</li> <li><input type="checkbox"/> Box No. VIII Certain observations on the international application</li> </ul>	

Date of submission of the demand 20.04.2005	Date of completion of this report 16.02.2006
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Storer, J Telephone No. +49 89 2399-7247



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ON PATENTABILITY

10/579207  
IAP9 Rec'd PCT/PTO 12 MAY 2005  
International application No.  
PCT/FI2004/000688

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
    - international search (under Rules 12.3 and 23.1(b))
    - publication of the international application (under Rule 12.4)
    - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

**Description, Pages**

1-6 as originally filed

**Claims, Numbers**

1-10 received on 27.08.2005 with letter of 23.08.2005

**Drawings, Sheets**

1/6-6/6 as originally filed

- a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
- 3.  The amendments have resulted in the cancellation of:
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):
- 4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

## 1. Statement

Novelty (N) Yes: Claims 1-10  
No: Claims

Inventive step (IS) Yes: Claims 1-10  
No: Claims

Industrial applicability (IA) Yes: Claims - 1-10  
No: Claims

## 2. Citations and explanations (Rule 70.7):

**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. The following document is referred to in this communication:  
D1 : US 3 918 444 A (HOFF ET AL) 11 November 1975 (1975-11-11)
  
2. The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and shows (the references in parentheses applying to this document): a plunger (20) intended for an inserter for an intrauterine device with a T-body, which plunger has a first end and a second end, and a first dimension, which is the longitudinal direction of the plunger, and the length of which plunger in its longitudinal direction is substantially larger than the diameter of the cross-section perpendicular to the longitudinal direction, and the cross-section of which plunger is substantially circular, and through which plunger an opening (e.g. 24) has been arranged in its longitudinal direction so that the longitudinal axis of the opening is substantially the same as the longitudinal axis of the plunger, wherein the opening at the first end of the plunger is arranged to expand in a direction perpendicular to the direction of the longitudinal axis to form a tip portion, so that the tip has at least one surface, which along a portion of the length of the tip turns at least 35° in relation to a first plane in parallel with the longitudinal axis (see column 3, lines 49-68 and figures 2 and 4).

The subject-matter of claim 1 differs from this known plunger in that the said at least one surface also turns at least 35° in relation to a plane that is perpendicular to said direction of the longitudinal axis, along at least a portion of the length of the tip portion.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as how to reduce the possibility of damage to the device to be inserted.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) since the available

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(SEPARATE SHEET)**

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prior art does not show or suggest providing a three-dimensional form within the opening of the first end of the plunger as achieved by the said at least one surface also turning at least 35° in relation to a plane that is perpendicular to the longitudinal axis, along at least a portion of the length of the tip portion.

Claims 2-10 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

3. Reference signs have not been used throughout the claims, which would have been appropriate (Rule 6.2(b) PCT).
4. The documents D1 should have been identified in the description and the background art disclosed therein briefly discussed (Rule 5.1(a)(ii) PCT).

**Claims**

1. A plunger intended for an inserter for an intrauterine device with a T-body, which the plunger has
  - a first end and a second end, and
- 5 - a first dimension, which is the longitudinal direction of the plunger, and
  - the length of which plunger in its longitudinal direction is substantially larger than the diameter of the cross-section perpendicular to the longitudinal direction, and
  - the cross-section of which plunger is substantially circular, and
- 10 - through which plunger an opening has been arranged in its longitudinal direction so that the longitudinal axis of the opening is substantially the same as the longitudinal axis of the plunger, wherein the opening at the first end of the plunger is arranged to expand in a direction perpendicular to the direction of the longitudinal axis to form a tip portion,
- 15 so that the tip portion has at least one surface, which along at least a portion of the length of the tip portion turns at least 35° in relation to a first plane in parallel with the longitudinal axis, characterised in that said at least one surface turns also at least 35° in relation to a plane that is perpendicular to said direction of the longitudinal axis, along at least a portion of the length of the tip portion.
- 20 2. A plunger according to claim 1, characterised in that said at least one surface turns 90° in relation to the first plane and 90° in relation to the plane at an angle.
3. A plunger according to any previous claim, characterised in that the tip portion has two surfaces.
- 25 4. A plunger according to claim 3, characterised in that said two surfaces form a surface pair.
5. A plunger according to claim 4, characterised in that the surfaces forming the surface pair of said surface pair are mirror images of each other in relation to a second plane in parallel with the longitudinal axis, whereby this second plane is 30 perpendicular to said first plane.
6. A plunger according to any previous claim, characterised in that it has in addition at least one surface, which is substantially in parallel with said first plane.

7. A plunger according to any previous claim, **characterised** in that the tip portion has four surfaces.
8. A plunger according to claim 7, **characterised** in that said four surfaces form two surface pairs, which are mirror images of each other in relation to said first plane in parallel with the longitudinal axis.  
5
9. A plunger according to claim 8, **characterised** in that in at least one surface pair the surfaces forming the surface pair are mirror images of each other in relation to a second plane in parallel with the longitudinal axis, whereby the second plane is perpendicular to said first plane.
10. 10. A plunger according to claim 8 or 9, **characterised** in that said surface pairs are connected with each other.